

**Opinion on the compulsory use of the anti-Covid vaccine**

With this own-initiative opinion, the CIEB intends to assess the critical aspects of the current vaccination campaign, in Italy as in other European countries, of which many Italians are becoming aware, sometimes with exasperated reactions in the absence of consistent and verifiable information.

To this end, it is useful to note that there is a widespread awareness that the marketing authorisation of the so-called anti-Covid vaccines has been granted on a "conditional" and temporary basis, and with exclusive reference to those based on nucleic acids, on the basis of European Commission Regulation No 507/2006 of 29 March 2006, which expressly applies to "medicinal products" for which "complete clinical data on safety and efficacy have not been provided" (Article 2, and Article 4, no. 1).

It should be noted in this regard that the conditions for granting the authorisation in question include the fact that the medicinal products in question meet 'unmet medical needs' (Article 4, no. 1, c) and that this condition could not have been fulfilled if the Ministry of Health had not adopted, in November 2020, the first of the ministerial circulars concerning the Guidelines for the home treatment of patients suffering from Covid (the so-called "watchful waiting and paracetamol"), which in fact hindered the development of therapies already known before the grant of this authorisation, which took place in December 2020.

It should also be noted that, according to the aforementioned Regulation 507/2006, the renewal of the authorisations granted - which are valid for 12 months - may take place only if the beneficiary fulfils 'the specific obligation to complete ongoing studies or to conduct new studies', in order to provide the clinical data that it had not produced before the authorisations were granted (Article 5, no. 1), and that the application for renewal must be submitted 'at least six months before the expiry of the conditional authorisation', a deadline which, for some vaccines, expired in June 2021 (Article 6, no. 2).

At the same time, there is an emerging awareness that the two main international organisations operating at European regional level, the Council of Europe and the European Union, have deemed it necessary to reaffirm freedom of vaccine choice in order to prevent the introduction of unlawful discrimination between vaccinated and unvaccinated persons. First, the Parliamentary Assembly of the Council of Europe intervened in this regard in Resolution 2361(2021) of 27 January 2021, which called for 'no one to be put under political, social or other pressure to vaccinate if they do not wish to do so themselves'. Second, the European Union intervened through Regulation 2021/953 of the European Parliament and of the Council of 14 June 2021, which, among other things, aims to avoid 'any direct or indirect discrimination against people who have chosen not to be vaccinated'.

While Italians, even in the absence of transparent institutional communication, strive to acquire a greater critical awareness of the political management of the Covid emergency, also with a view to informing their consent to an eventual vaccination, the Government continues in its action to promote - through increasingly coercive, controversial and contested measures and regulatory methods - the vaccination campaign, by continuously extending the state of emergency even in the face of a changed health situation, by obliging members of specific professional categories to be

vaccinated according to a targeted approach (first health workers, then teachers, then members of the police and armed forces), and by adopting measures that surreptitiously force large sections of the population to be vaccinated.

The action of the Government prefigures possible violations of fundamental rights and freedoms guaranteed by the Italian system, with specific reference to the right to health enshrined in Article 32 of the Constitution, which puts, on a systematic level, the individual right before the collective interest ("The Republic protects health as a fundamental right of the individual and in the interest of the community": and not vice versa). Article 32, as is well known, also establishes that "No one may be obliged to undergo a given medical treatment except by provision of law", where "law" can only mean, in the spirit of the republican Constitution approved in 1948 after the fascist experience, a legislative measure adopted by Parliament at the end of an open and transparent democratic debate, which in Italy to date has clearly been lacking.

In any event, even if a Parliament were to adopt such a law, Article 32 is concerned to ensure that such a law does not end up violating fundamental human rights ("The law may in no case violate the limits imposed by the respect for the human person"). The Italian Government's actions also conflict with certain general principles of international and European law, as well as with the fundamental principles of bioethics, such as the precautionary principle, as formulated in the 1992 Rio de Janeiro Declaration and transposed by the Treaty on the Functioning of the European Union; the principle of informed consent, enshrined in instruments of a deontological nature (the Nuremberg Code of 1947, the 1964 Helsinki Declaration) and of a legal nature (the 1966 International Covenant on Civil and Political Rights, ratified by Italy in 1978); as well as the principles of beneficence, non-maleficence and equal access to health care, which have also inspired the European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to Applications of Biology and Medicine (known as the Convention on Human Rights and Biomedicine), signed in 1997 in Oviedo and ratified by Italy in 2001.

In this regard, it should be noted that, although Italy has failed to deposit the instrument of ratification of the Oviedo Convention (with the consequence that the Convention itself has not yet entered into force in the Italian legal system), its hermeneutic value is indisputable and cannot be ignored by domestic legal operators. The bio-legal dimension of the problem in question is made even more complex by the divisions that tear apart the scientific community regarding the effectiveness and safety of the vaccines, divisions that, a year after putting these vaccines on the markets, multiply rather than reduce and assume increasing importance in the eyes of public opinion, despite the climate of open favour that the media grant, virtually unanimously, to the vaccination campaign.

In any case, beyond the contrast between conflicting clinical and epidemiological data, what appears particular to the CIEB is the fact that nucleic acid vaccines are still the only result of the efforts made, over a period of two years, by local and international scientific research policies in the fight against the Sars-Cov-2 virus and Covid disease. In the eyes of public opinion and of a substantial part of the scientific community, this has excluded from the range of tools available to contemporary medicine any other approach, whether of a preventive nature - from hygiene and prophylaxis, to a scientific analysis of the causes of the disease and its spread, to the development of traditional vaccines (protein-based or from an attenuated pathogen) - or of a clinical-therapeutic nature.

On the basis of the above considerations, the CIEB hopes first of all that the Italian Government will review the methods and objectives of the management of the Covid emergency, with particular reference to the possible further extension of the current vaccination campaign, with the specific aim of safeguarding the public's right to health through the enhancement of a precautionary approach that adequately takes into account the documented scientific uncertainties regarding the efficacy, safety and actual capacity of the vaccines themselves to combat the spread of the Sars-Cov-2 virus. In this perspective, compulsory vaccination should be usefully replaced by non-invasive tools aimed at monitoring the spread of infections and effectively combating the disease from the earliest stages of its onset.

The CIEB also believes it is necessary to bring the principles and values that inspire bioethical reflection back to the centre of the management of the Covid emergency and, to this end: 1) recommends that the Italian Government deposit the instrument of ratification of the 1997 Oviedo Convention; 2) recommends that the Italian Government promote, in accordance with art. 28 of the Convention itself, an adequate public debate on the fundamental questions raised by the development of biology and medicine in the light in particular of their medical, social, economic, ethical and legal implications.

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